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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,321	08/04/2003	Unchalee Kositprapa	AXP-0003B	7853

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EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	
ART UNIT	**PAPER NUMBER**
1616	
MAIL DATE	**DELIVERY MODE**
09/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/634,321	KOSITPRAPA, UNCHALEE	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/21/07*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,6,7 and 20-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 6-7, and 20-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-2, 6-7, and 20-37 are pending. Applicant previously cancelled claims 3-6 and 8-19. Claims 1 and 20-21 were amended. Receipt and consideration of Applicant's terminal disclaimers, amended claims, and remarks/arguments submitted on June 21, 2007 are acknowledged.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 21, 2007 has been entered.

Terminal Disclaimer(s)

The terminal disclaimers filed on June 21, 2007 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of (i) U.S. Patent No. 6,174,548; (ii) U.S. Patent No. 6,602,522; and (iii) U.S. Patent No. 6,733,778 have been reviewed and are accepted. The terminal disclaimers have been recorded.

Specification

The objection to the specification for the improper use of the trademarks AVICEL®, PLASDONE®, and EUDRAGIT® **is withdrawn**, per Applicant's amendments writing said trademarks in all capital letters.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 32, 34, and 36 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** per Applicant's claim amendments clarifying the nature of the claimed invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites the limitation "the enteric coating" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The rejection of claims 32, 34, and 36 under 35 U.S.C. 102(e) as being anticipated by Kanios et al. (U.S. Patent 5,719,197 **is withdrawn** per Applicant's claim amendments specifying that the water soluble and water-insoluble binders are present in the claimed composition in a non-zero amount.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The rejection of claims 1, 7, and 20-37 under 35 U.S.C. 103(a) as being unpatentable over Morella et al. (94/05262) in view of Kanios et al. (U.S. Patent No. 5,719,197) **is maintained** for the reasons of record set forth on pages 4-6 (Morella) and 7-8 (Kanios) and in the office action mailed on April 13, 2006 and on pages 5-6 of the office action mailed on December 19, 2006. Upon reconsideration, claims 2 and 6 are appended to this rejection for the reasons of record per Morella's teaching of cellulose enteric polymer coatings. In summary, **claims 1-2, 6-7, and 20-37 are rejected 37 under 35 U.S.C. 103(a) as being unpatentable over Morella et al. (94/05262) in view of Kanios et al. (U.S. Patent No. 5,719,197).**

Response to Arguments

Applicant's arguments filed June 21, 2007 have been fully considered but they are not persuasive. Applicant has traversed the instant rejection by arguing: (1) an ordinary skilled

artisan at the time of the instant invention allegedly would not be motivated to combine the teachings of Morella and Kanios, because Kanios is concerned with topical administration and Morella is directed towards oral pharmaceutical dosage forms; and (2) the expertise required of an ordinary skilled artisan in the field of oral dosage forms is different that the expertise required in the field of topical dosage forms.

The Examiner respectfully disagrees with Applicant. Regarding (1), it would have been obvious to an ordinary skilled artisan to utilize any of the drugs taught by Kanios in an oral controlled-release dosage form, because as Applicant admitted on the record, drugs formulated in a controlled-release dosage form are not patentably distinct: "Applicant disagrees with the characterization that the species disclosed are patentably distinct" (see Applicant's response to the restriction requirement submitted on September 22, 2005). In other words, there is no patentable distinction between the active agents included in a controlled release formulation, and an ordinary skilled artisan would have been motivated to rely upon the teachings of Kanios as a convenient concise listing of a wide variety of pharmaceutical active agents, which in the course of routine experimentation and optimization, would be substituted for the actives taught by Morella to obtain controlled release formulations of these other active agents. Furthermore, a person of ordinary skill in the art would have been motivated to utilize Morella's' teachings as the basis of controlled release formulations comprising either anti-diabetic drugs or HMG-CoA reductase inhibitors, because the advantages of controlled release formulations over rapid release formulations (i.e. typical formulations) are especially desirable in treatments requiring prolonged drug administration. An ordinary skilled artisan would have been motivated to modify the sustained release formulations of Morella to comprise anti-diabetic or HMG-CoA reductase

inhibitors because these drugs are used to treat chronic diseases (i.e. diabetes and hyperlipidemia (i.e. high cholesterol)), which requires prolonged treatment. An ordinary skilled artisan would have been further motivated to utilize a controlled release formulation, because said formulations would be expected to enhance patient compliance due to less frequently required administration of drug to obtain therapeutic efficacy. Thus, the instant rejection is deemed proper and an ordinary skilled artisan at the time of the instant invention would have had a reasonable expectation of success upon modification of Morella to include any of the drugs taught by Kanios.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 1-2, 4, 7, and 10 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4, 7-9 of U.S. Patent No. 6,174,548

(USPN '548) in view of Morella (WO 94/05262) and view of Kanios et al. (U.S. Patent No. 5,719,197) ("Kanios") **is withdrawn**, per Applicant's submission of a proper terminal disclaimer that has been accepted.

The rejection of claims 1, 6-7, 21, and 22 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4, 5-11, 16, and 18-19 of U.S. Patent No. 6,602,522 (USPN '522) in view of Kanios et al. (U.S. Patent No. 5,719,197) ("Kanios") **is withdrawn**, per Applicant's submission of a proper terminal disclaimer that has been accepted.

The rejection of claims 1-2, 5-11, and 13-16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4, 7-9 of U.S. Patent No. 6,733,778 (USPN '778) in view of Morella (WO 94/05262) and Kanios et al. (U.S. Patent No. 5,719,197) ("Kanios") **is withdrawn**, per Applicant's submission of a proper terminal disclaimer that has been accepted.

Response to Arguments

Applicant's arguments, see pages 17-18, filed June 21, 2007, with respect to the above-cited rejections on the ground of nonstatutory obviousness-type double patenting have been fully considered and are persuasive. The above-cited rejections on the ground of nonstatutory obviousness-type double patenting have been withdrawn.

Conclusion

Claims 1-2, 6-7, and 20-37 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James H. Alstrum-Acevedo
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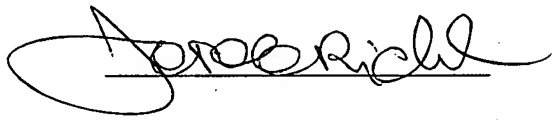

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